IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

JOSEPH HAVERL,	:	**CIVIL ACTION NO. 1:20-CV-2361**
	:	
Plaintiff	:	**(Judge Conner)**
	:	
v.	:	
	:	
HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS and OSARTIS GMBH f/k/a AAP BIOMATERIALS GMBH,	:	
	:	
Defendants	:	

MEMORANDUM

Plaintiff Joseph Haverl brings a products liability and negligence suit against defendants Howmedica Osteonics Corporation doing business as Stryker Orthopaedics ("Stryker") and Osartis GMBH formerly known as AAP Biomaterials GMBH ("Osartis") (collectively "defendants") concerning an unsuccessful knee replacement surgery. Stryker moves to dismiss Haverl's claims pursuant to Rule of Federal Civil Procedure 12(b)(6). We will partially grant Stryker's motion.

I. Factual Background & Procedural History

Stryker is an American corporation engaged in the business of selling, *inter alia*, bone cements used in knee replacement surgeries. (See Doc. 42 ¶¶ 2, 14-16). Stryker markets two bone cement products relevant to this litigation: a medium-viscosity cement called "Simplex P" and a high-viscosity cement called "Simplex HV." (See id. ¶ 16). Simplex P and Simplex HV are both polymethylmethacrylate ("PMMA") cements. (See id. ¶¶ 17, 39). During knee replacement surgery, medical

professionals make PMMA cements by combining the cement's powder and liquid components in a delicate mixing process. (See id. ¶¶ 15, 38). The significance of a cement's viscosity is the way that viscosity impacts the mixing process. (See id. ¶¶ 15, 46). Distilling the complexities of medical science down to their barest essence: the lower the cement's viscosity, the more akin the cement remains to a liquid during the mixing process. (See id. ¶¶ 48-49, 54). The higher the viscosity, the more quickly the cement becomes akin to a dough. (See id. ¶¶ 21, 48). It is harder to remove air from a dough-like substance than a liquid-like substance. (See id. ¶¶ 21, 48). The more air left in the cement at the end of the mixing process, the more porous the cement. (See id. ¶ 19). The more porous the cement, the more prone the cement is to failure after application. (See id. ¶¶ 20, 25, 50, 135, 137-38). Thus, high-viscosity cements, while quicker to prepare, are generally more prone to failure than less viscous cements. (See id. ¶¶ 70, 76).

A. Development of Simplex HV

Stryker first started selling Simplex P several decades ago. (See id. ¶ 16). A successful product, Simplex P was, as of 2013, the most used PMMA cement in the United States, controlling roughly 60% of the PMMA market. (See id. ¶ 17). Up until 2013, Stryker marketed the medium-viscosity Simplex P specifically as being safer than competing high-viscosity cements because of its lower porosity. (See id. ¶¶ 18-21). Nonetheless, Stryker decided around 2010 that it wanted to enter the growing market for high-viscosity bone cements. (See id. ¶¶ 22-24). Stryker initially tried to develop its own high-viscosity cement but ultimately decided it was more

cost effective to purchase an existing high-viscosity cement—a product called "BonOs R" from the German company Osartis. (See id. ¶¶ 24-28).

Osartis and Stryker cooperated to obtain regulatory approval to sell and market BonOs R in the United States. (See id. ¶¶ 31-34). The two companies jointly conducted the testing required for marketing the product in the United States and worked together to adjust the formula for BonOs R in response to FDA concerns. (See id. ¶¶ 29-31, 33). They also collaborated on the instructions for using BonOs R. (See id. ¶ 32). Stryker and Osartis obtained regulatory approval for their high-viscosity cement in 2013 and began selling BonOs R under the name "Simplex HV" throughout the United States. (See id. ¶¶ 36-37).

B. Haverl's Knee Replacement

Haverl underwent knee replacement surgery on his right knee on or about June 8, 2018. (See id. ¶ 79). The surgeon who performed Haverl's surgery, Dr. Scott King, D.O., used Simplex HV to affix the components of Haverl's new artificial knee to his existing bones. (See id. ¶¶ 79-80). Following completion of the surgery, Haverl began feeling "sharp and stabbing" pains in his right knee that were made "worse by movement." (See id. ¶ 81). On or about December 18, 2018, Dr. King conducted a "revision surgery" on Haverl's right knee to address the pain. (See id. ¶ 83). During the second surgery, Dr. King observed that the cause of Haverl's pain was the "mechanical loosening" of the tibial component of Haverl's artificial knee. (See id.) While the Simplex HV bonded properly with Haverl's bone, it purportedly failed to bond with the metal portion of the tibial component. (See id.) Dr. King rebonded the tibial component to the bone using a low-viscosity cement. (See id.

¶ 84). Haverl alleges he continues to experience pain, suffering, and physical impairment as a result of his failed knee replacement. (See id. ¶ 85).

C. Alleged Shortcomings of Simplex HV

Haverl alleges several shortcomings in Simplex HV's design, manufacturing, and instructions contributed to his injury. (See id. ¶¶ 38-78, 114-16, 147-50, 166-67, 190, 196, 207).

- Haverl alleges Simplex HV must be applied at precisely the right phase of the mixing process for it to adhere properly, particularly to metal. (See id. ¶¶ 40-42). When Simplex HV is applied outside of that phase, the cement loses 90 percent of its adhesion strength. (See id. ¶ 41). Harverl claims it is difficult for medical professionals to determine when Simplex HV is in the optimal phase for application or when it has left the optimal phase and become unlikely to properly adhere. (See id. ¶ 40).

- Haverl alleges that Simplex HV's viscosity differs significantly from package to package, even when the packages come from the same manufacturing lots. (See id. ¶¶ 45, 129). The difference in viscosity can alter the optimal moment for application by as much as two minutes. (See id. ¶¶ 45-47). Defendants never apprised customers or medical professionals of this variance. (See id. ¶¶ 130-31).

- Haverl alleges that Simple HV "depth of intrusion into bone" was significantly less than that of Simplex P and, at least under certain circumstances, less than that of a rival high-viscosity cement called Palacos R. (See id. ¶¶ 67, 144, 229-31).

- Haverl alleges that defendants failed to inform medical professionals, including Dr. King, about the risks posed by Simple HV's overall porosity problem, inconsistency from package to package, and inferior bone intrusion, or how to safely reduce the porosity of Simplex HV. (See id. ¶¶ 55-59, 69, 119-21, 124, 133, 135-42, 232). Specifically, he alleges they failed to instruct medical professionals, including Dr. King, that porosity can be safely decreased by prechilling Simplex HV or by employing certain "vacuum mixers." (See id. ¶¶ 55, 57, 59, 60, 69).

Haverl alleges knee replacements utilizing Simplex HV are several times more likely to be affected by "early aseptic loosening"—the premature loosening of the bond between a metal component of the artificial knee and the patient's bone—than surgeries conducted using Simplex P or the rival high-viscosity cement, Palacos R. (See id. ¶¶ 33, 71, 77, 153, 225-26, 228). Aseptic loosening results in pain to the patient and damage to the patient's bone, frequently requiring revision surgery to replace the artificial knee implant and possibly reconstruct the damaged bone. (See id. ¶¶ 71-75). Revision surgeries carry higher risk for complications and lasting limitations on the patient's range of motion. (See id. ¶ 75).

D. Obfuscation of Simplex HR's Shortcomings

Haverl also alleges defendants were aware of Simplex HV's shortcomings. (See id. ¶¶ 33-35, 68, 126, 128, 130, 173, 226-28, 234). Yet defendants allegedly marketed Simplex HV and provided instructions for using Simplex HV that obfuscated these shortcomings. (See id. ¶¶ 59, 66-70, 142-46, 170-72, 177, 181, 188, 199, 229-33). For example, Haverl alleges that the draft instructions for Simplex HV included a recommendation that medical professionals prechill Simplex HV before use. (See id. ¶¶ 59-60). Haverl claims defendants removed this instruction because "they knew testing would confirm that prechilled Simplex HV has no benefit over Simplex P—but has considerable additional risk." (See id. ¶ 61). Haverl also alleges that defendants ceased criticizing high-viscosity cements in their advertising for Simplex P after Simplex HV entered the market in 2013. (See id. ¶¶ 62-63). Instead, defendants purportedly marketed Simplex HV as being as "safe and effective" as Simplex P despite knowing that Simplex HV was less safe and less effective than

Simplex P or, at least in terms of bone intrusion, the competing high-viscosity cement, Palacos R. (See id. ¶¶ 33-34, 64-70, 76, 144-46, 153, 229, 231). Harverl asserts that if defendants had marketed Simplex HV honestly and included warnings addressing the cement's shortcomings, medical professionals, like Dr. King, would have refrained from using Simplex HV altogether or taken greater effort to ensure the cement was properly mixed and applied. (See id. ¶¶ 133, 147-48).

E. Procedural History

Haverl filed the instant action against Stryker, Osartis, AAP Implantate AG, and AAP Implants, Inc., on December 16, 2020. He voluntarily dismissed his claims against Implantate AG and AAP Implants, Inc. The action now proceeds under Haverl's second amended complaint. As of today's date, Haverl has not yet served Osartis with his complaint. Stryker now moves to dismiss or limit all claims. The motion is fully briefed and ready for disposition.

II. Legal Standard

Rule 12(b)(6) of the Federal Rules of Civil Procedure provides for the dismissal of complaints that fail to state a claim upon which relief may be granted. See FED. R. CIV. P. 12(b)(6). When ruling on a motion to dismiss under Rule 12(b)(6), the court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (quoting Pinker v. Roche Holdings, Ltd., 292 F.3d 361, 374 n.7 (3d Cir. 2002)).

Federal notice and pleading rules require the complaint to provide "the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Phillips, 515 F.3d at 232 (alteration in original) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). To test the sufficiency of the complaint, the court conducts a three-step inquiry. See Santiago v. Warminster Township, 629 F.3d 121, 130-31 (3d Cir. 2010). In the first step, "the court must 'tak[e] note of the elements a plaintiff must plead to state a claim.'" Id. at 130 (alteration in original) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 675 (2009)). Next, the factual and legal elements of a claim must be separated; well-pleaded facts are accepted as true, while mere legal conclusions may be disregarded. Id. at 131-32; see Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009). Once the court isolates the well-pleaded factual allegations, it must determine whether they are sufficient to show a "plausible claim for relief." Iqbal, 556 U.S. at 679 (citing Twombly, 550 U.S. at 556); Twombly, 550 U.S. at 556. A claim is facially plausible when the plaintiff pleads facts "that allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678.

III. Discussion

Haverl's second amended complaint advances eleven claims against defendants.[1] (See Doc. 42). It asserts three strict products liability claims for design defect, manufacturing defect, and failure to warn (Counts I, II, & III). He also

[1] We will refer to Haverl's second amended complaint (Doc. 42) as "complaint" throughout the rest of this memorandum for the sake of concision.

brings claims for breach of express warranty (Count IV), breach of implied warranty (Count V), negligence (Count VI), negligent misrepresentation (Count VII), fraudulent misrepresentation (Count VIII), fraudulent concealment (Count IX), violation of Pennsylvania's unfair trade practices and consumer protection laws (Count X), and punitive damages (Count XI). Stryker moves to dismiss all of Haverl's claims pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing Haverl's claims are either inadequately pled or barred as a matter of law. (See Doc. 50 at 2 (citing FED. R. CIV. P. 12(b)(6))). Haverl withdraws his breach of implied warranty, fraudulent misrepresentation, and fraudulent concealment claims. (See Doc. 51 at 9, 13). He also withdraws his claims under Pennsylvania's unfair trade practice and consumer protection laws. (See id.) We will address Haverl's remaining claims *seriatim*.

A. Counts I-III: Strict Products Liability

Stryker contends that it is immune from Haverl's strict products liability claims under comment k to the Restatement (Second) of Torts § 402A, which exempts "[u]navoidably unsafe products" from the application of strict liability. (See Doc. 50 at 6 (citing RESTATEMENT (SECOND) OF TORTS § 402A (AM. LAW INST. 1979))). The Pennsylvania Supreme Court has adopted Section 402A of the Restatement and applied comment k to preclude strict products liability lawsuits against manufacturers of prescription drugs. See Ebert v. C.R. Bard, Inc., No. 20-2139, 2021 WL 2656690, at *4 (3d Cir. June 24, 2021) (citing Hahn v. Richter, 673 A.2d 888, 889-91 (Pa. 1996), certified question accepted, 260 A.3d 81 (Pa. 2021)). However, the Pennsylvania Supreme Court has never decided whether comment k also

applies to manufacturers of prescription medical devices. See id. at *4-5. Recently, our court of appeals certified a question to the Pennsylvania Supreme Court regarding the degree to which prescription medical devices are subject to strict liability torts. See id. at *6. Consequently, we will deny Stryker's motion to dismiss Counts I, II, and III pending resolution of the appeal in Ebert v. CR Bard Inc., No. 20-2139 (3d Cir.).

B. Count IV: Breach of Express Warranty

To state a claim for breach of express warranty, Haverl must plead facts indicating that he relied on an "actual affirmation of fact or a promise by the seller" as a basis for his bargain with Stryker. See 13 PA. CONS. STAT. § 2313; see also Mueller v. Sunbean Prods. Inc., 535 F. Supp. 3d 351, 354-55 (E.D. Pa. Apr. 22, 2021) (collecting cases). A product's advertising may serve as the basis for the bargain if the plaintiff can show that they "read, heard, saw or knew of the advertisement containing the affirmation of fact or promise." See, e.g., Ebert v. C.R. Bard, Inc., 459 F. Supp. 3d 637, 649 (E.D. Pa. 2020); Conley v. St. Jude Med., LLC, 482 F. Supp. 3d 268, 278 (M.D. Pa. 2020); Gross v. Stryker Corp., 858 F. Supp. 2d 466, 501 (W.D. Pa. 2012).

Haverl has not pled he engaged in any direct dealings with Stryker, was aware of Stryker's advertising, or in any way participated in the decision to use Simplex HV in his knee replacement surgery. Admitting this deficiency, Haverl contends that he has asserted a proper breach of express warranty claim because Stryker represented Simplex HV's efficacy to Haverl's doctor via Simplex HV's marketing. (See Doc. 51 at 9-10). Haverl cites no statutes or case law suggesting

Pennsylvania acknowledges a third-party-reliance theory of liability regarding breach of express warranty. Our own examination of Pennsylvania law reveals that it only allows for third parties to enforce an express warranty when (1) "the party issuing the warranty intends to extend the specific terms of the warranty to the third party (either directly, or through an intermediary)"; and (2) "the third party is aware of the specific terms of the warranty, and the identity of the party issuing the warranty." See Goodman v. PPG Indus., Inc., 849 A.2d 1239, 1246 (Pa. Super. Ct. 2004), aff'd, 885 A.2d 982 (Pa. 2005); see also Miller v. Heil Co., 525 F. Supp. 3d 612, 618 n.2 (W.D. Pa. 2021). Again, Haverl has not pled facts showing he had any awareness of Simplex HV's or Stryker's existence prior to the "revision" surgery on his knee. (See Doc. 42 ¶ 83); Goodman, 849 A.2d at 1246. We will dismiss Count IV without prejudice to afford Haverl the opportunity to state facts better supporting his breach of express warranty claim.

C. Count VI: Negligence

To state a claim for negligence under Pennsylvania law, a plaintiff must plead: "(1) a duty of care; (2) [a] breach of the duty; (3) a causal connection between the conduct and the resulting injury; and (4) actual loss or damage resulting to the plaintiff." See Farabaugh v. Pa. Tpk. Comm'n, 911 A.2d 1264, 1272-73 (Pa. 2006) (citation omitted); Berrier v. Simplicity Mfg., Inc., 563 F.3d 38, 61 (3d Cir. 2009) (quoting Phillips v. Cricket Lighters, 841 A.2d 1000, 1008 (Pa. 2003)). Haverl alleges Stryker had a duty to exercise ordinary care and breached that duty by negligently "designing, researching, testing, manufacturing, marketing, supplying, promoting,

distributing, approving, and selling" Simplex HV, as well as failing to warn Haverl and his doctors as to the dangers of Simplex HV. (See Doc. 42 ¶¶ 169, 171).

Stryker attacks several of Haverl's theories as to how Stryker breached its duty as being insufficiently pled or otherwise legally inadequate. (See Doc. 50 at 19; Doc. 52 at 9-10). In response to Stryker's arguments, Haverl withdraws his negligent testing and marketing theories, but insists his remaining theories are adequately pled. (See Doc. 51 at 11-12). On the whole, we agree with Haverl. He asserts sufficient facts from which to infer Stryker negligently designed Simplex HV so that its optimal adhesion phase is too difficult to identify, (see Doc. 42 ¶¶ 40-42), negligently manufactured the cement creating significant variances in the optimal phase from package to package, (see id. ¶¶ 45-47), and negligently failed to warn Haverl's doctor about the cement's shortcomings and quirks, (see id. ¶¶ 55-61). We find Haverl's negligent failure-to-warn theory to be barred by the learned-intermediary doctrine in so far as it pertains to Stryker's failure to warn Haverl. See Gurley v. Janssen Pharms., Inc., 113 A.3d 283, 292-93 (Pa. Super. Ct. 2015) (citing Cochran v. Wyeth, Inc., 3 A.3d 673, 676 (Pa. Super. Ct. 2010)). We will dismiss Haverl's negligence claim with prejudice to the extent that it relies on negligent testing, negligent marketing, or the negligent failure to warn Haverl.

D. Counts VII: Negligent Misrepresentation

A claim for negligent misrepresentation requires, as a threshold matter, that the plaintiff state facts that give rise to a duty of care owed to them by the defendant. See Bilt-Rite Contractors, Inc. v. Architectural Studio, 866 A.2d 270, 277-78, 280 (Pa. 2005). Once that threshold question is satisfied, the plaintiff

then must plead facts plausibly supporting the following elements: "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known its falsity; (3) with an intent to induce another to act on it; and; (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." Bortz v. Noon, 729 A.2d 555, 561 (Pa. 1999); see also Gibbs v. Ernst, 647 A.2d 882, 890 (Pa. 1994).

Stryker argues that Haverl's pleadings fail to meet the standard set by Federal Rule of Civil Procedure 9(b). (See Doc. 50 at 16-17; Doc. 52 at 10-11). Rule 9(b) requires that claims "alleging fraud or mistake" state the circumstances of the fraud or mistaken "with particularity," a standard viewed to be significantly more rigorous than the Rule 12(b)(6) standard. See FED. R. CIV. P. 9(b); United States *ex rel.* Bookwalter v. UPMC, 946 F.3d 162, 176 (3d Cir. 2019). However, district courts within the Third Circuit are divided as to whether negligent misrepresentation falls within the ambit of Rule 9(b). See McLaughlin v. Bayer Corp., 172 F. Supp. 3d 804, 828 (E.D. Pa. 2016) (collecting cases).

Assuming *arguendo* that Rule 9(b) applies to Haverl's claim, we find Haverl meets the heighted Rule 9(b) standard. Haverl avers Stryker advertised Simplex HV as being as safe and effective as Simplex P in their marketing materials. (See Doc. 42 ¶¶ 63-64, 69-70, 142-44, 192). These statements allegedly misrepresented the dangers and shortcomings of Simplex HV. (See id. ¶¶ 66-67, 142-44, 192-93). Haverl also avers his physician relied on these marketing materials in making the decision to use Simplex HV during his knee replacement surgery. (See id. ¶¶ 193-95). Haverl admittedly does not identify precisely which advertisement or marketing

material Dr. King relied upon, but Rule 9(b) does not require plaintiffs "to plead anything more, such as the date, time, place, or content of every single allegedly false . . . claim." See Bookwalter, 946 F.3d at 176. Hence, Haverl has placed Stryker on adequate notice of the "precise misconduct with which [it is] charged." See Alpizar-Fallas v. Favero, 908 F.3d 910, 919 (3d Cir. 2018). We will deny Stryker's motion to dismiss this claim.

E Counts XI: Punitive Damages

Under Pennsylvania law, punitive damages may only be awarded to punish "conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others." See Hutchison *ex rel.* Hutchison v. Luddy, 870 A.2d 766, 770 (Pa. 2005) (quoting RESTATEMENT (SECOND) OF TORTS § 908(2)). The defendant's state of mind is vital to any assessment of the propriety of punitive damages—"[t]he act, or the failure to act, must be intentional, reckless or malicious." See id. (quoting Feld v. Merriam, 485 A.2d 742, 748 (Pa. 1984)). Hence, a claim for punitive damages must be supported by averments suggesting that "(1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." Id. at 772 (citing Martin v. Johns-Manville Corp., 494 A.2d 1088, 1097-98 (Pa. 1985)).

Stryker contends Haverl fails to aver any facts supporting a claim for punitive damages. (See Doc. 50 at 22; Doc. 52 at 12-13). We disagree. Haverl alleges Stryker was aware of Simplex HV's inadequacies and yet touted the cement to physicians as being as safe and effective as the more-established medium-

viscosity Simplex P without informing them of the Simplex HV's shortcomings. (See Doc. 42 ¶¶ 61, 66-69, 78, 126, 128-29, 134, 224-36). Under the facts pled, it is not implausible that Stryker's alleged disregard for Simplex HV's shortcoming reaches the level of "outrageous." See Hutchison, 870 A.2d at 770. Development of a factual record is appropriate. We will deny Stryker's motion to dismiss this claim.

IV. Conclusion

For the above reasons, we will grant in part and deny in part Stryker's motion to dismiss pursuant Federal Rule of Civil Procedure 12(b)(6). An appropriate order shall issue.

/S/ CHRISTOPHER C. CONNER
Christopher C. Conner
United States District Judge
Middle District of Pennsylvania

Dated: August 31, 2022